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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,501	10/02/2003	David Lauffer	VPI/98-21 DIV US	8260

27916 7590 04/27/2007  
VERTEX PHARMACEUTICALS INC.  
130 WAVERLY STREET  
CAMBRIDGE, MA 02139-4242

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/677,501	Applicant(s) LAUFFER ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election without traverse of group IV, species of example 2, for the method of treating Alzheimer's disease in the reply filed on Feb. 2, 2007 is acknowledged.

The elected invention, claim 20 (claim 21 as originally filed but renumbered as 20), limited to treating Alzheimer's disease using 3,4,5-trimethoxy-N-[2-[,ethyl[4-(3-pyridinyl)-1-[3-(3-pyrinyl)propyl]butyl]amino-2-oxyethyl]- $\alpha$ -oxo- benzeneacetamine (example 2), is prosecuted. Please note that no generic claim read on the elected invention. Therefore, no generic claims will be prosecuted. Claims 1-19, 21-24 and the remaining subject matter of claim 20, are withdrawn from consideration being drawn to the non-elected invention.

2. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Please note that, example 2 is a compound drawn to the compound wherein the K moiety of formula I disclosed on page 4 of the specification is hydrogen. Nowhere in the specification was any description that such compound has any biological activity. Description of biological activity is limited to compounds of formula I which does not encompass the elected K is H compounds.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Please note that, example 2 is a compound drawn to the compound wherein the K moiety of formula I disclosed on page 4 of the specification is hydrogen. Nowhere in the specification was any description that how the elected compound can be administered, site, dosage or efficacy, for treating Alzheimer's disease in vivo or ex vivo. Description of biological activity is limited to compounds of formula I which does not encompass the elected K is H compounds, thus, lack sufficient enablement.

Art Unit: 1625

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. US 6,242,468 in view of Azzouz et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

Li et al generically claimed the instant method, see col. 22, claim 4 and col. 21 claim 1, wherein K is C1 alkyl (line 63).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant elected compound for the same method of treating Alzheimer is that the prior art is K is methyl compound while the instant elected example 2, has the K being H.

Azzouz et al. taught that using animal model in neurodegeneration, the replacement of a glycine to alanine would result in loss of motoneurons.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above Li et. Al. '468 reference placed analogous neurotrophic compounds in artisan's possession. One having ordinary skill in the art would be motivated to replace the alanine derivatives of the prior art with a glycine derivative because in analogous art by Azzouz et al. one skilled in the art would be suggested that such replacement is expected to be beneficial since

Art Unit: 1625


Azzouz et al. taught that the glycine derivative would prevent neuronal loss while replacing glycine with alanine, the alanine derivative would not sustain neurite growth or survival.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
April 24, 2007

  
Celia Chang  
Primary Examiner  
Art Unit 1625